

Food and Drug Administration, HHS

§ 173.360

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme prepara-

tions in accordance with the following conditions:

(a) The materials consist of one or more of the following:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Cellulose triacetate	May be used as a fixing material in the immobilization of lactase for use in reducing the lactose content of milk.
Diethylaminoethyl-cellulose	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Glutaraldehyde	Do.
Periodic acid (CAS Reg. No. 10450-60-9) .	
Polyethylenimine reaction product with 1,2-dichloroethane (CAS Reg.No. 68130-97-2) is the reaction product of homopolymerization of ethylenimine in aqueous hydrochloric acid at 100 °C and of cross-linking with 1,2-dichloroethane. The finished polymer has an average molecular weight of 50,000 to 70,000 as determined by gel permeation chromatography. The analytical method is entitled "Methodology for Molecular Weight Detection of Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-200), 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC .	May be used as a fixing material in the immobilization of glucoamylase enzyme preparations from <i>Aspergillus niger</i> for use in the manufacture of beer. May be used as a fixing material in the immobilization of: 1. Glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter. 2. Glucoamylase enzyme preparations from <i>Aspergillus niger</i> for use in the manufacture of beer. Residual ethylenimine in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography-mass spectrometry. The residual ethylenimine is determined by an analytical method entitled "Methodology for Ethylenimine Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Residual 1,2-dichloroethane in the finished polyethylenimine polymer will be less than 1 part per million as determined by gas chromatography. The residual 1,2-dichloroethane is determined by an analytical method entitled, "Methodology for Ethylenedichloride Detection in Polyethylenimine," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS-215), 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., Washington, DC, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) The fixed enzyme preparation is washed to remove residues of the fixing materials.

[48 FR 5716, Feb. 8, 1983, as amended at 52 FR 39512, Oct. 22, 1987; 55 FR 12172, Apr. 2, 1990; 59 FR 36937, July 20, 1994; 61 FR 4873, Feb. 9, 1996; 61 FR 14245, Apr. 1, 1996]

§ 173.360 Octafluorocyclobutane.

The food additive octafluorocyclobutane may be safely used as a propellant and aerating agent in foamed or sprayed food products in accordance with the following conditions:

(a) The food additive meets the following specifications:

99.99 percent octafluorocyclobutane.

Less than 0.1 part per million fluoroolefins, calculated as perfluoroisobutylene.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, and propane, as a propellant and aerating agent for foamed or sprayed food products, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive:

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, octafluorocyclobutane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".